AUG - 3 2007

K071341

11. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Premarket Notification [510(K)] Summary
(per 21 CFR 807.92)

Company Name
Medivance, Inc.
1172 Century Drive, Suite 240
Louisville, Colorado 80027

Contact Person: Lynne Aronson
Director, Regulatory Affairs and Quality Assurance
Telephone: 303-926-1917
Facsimile: 303-926-1924

Device Name
Trade/Proprietary Name: Arctic Sun™ Temperature Management System, Model 2000
Common/Usual Name: Hypo/Hyperthermia System
Classification Name: System, Thermal Regulating (per 21 CFR 870.5900)

Predicate Devices
The Arctic Sun™ Temperature Management System, Model 200, is substantially equivalent to the following predicate devices:

Arctic Sun Temperature Management System – Model 2000	Medivance, Inc.	K010338
MediTherm II Series 5900 Hyper/Hypothermia System	Gaymar Industries	K912051
Blanketrol II Hyper/Hypothermia System	Cincinnati Sub Zero	K811742

Intended use of the device
The Arctic Sun Temperature Management System Model 2000 is a thermal regulating system, indicated for monitoring and controlling patient temperature.

Description of the Device
The Arctic Sun Temperature Management System is a device used to monitor and control patient temperature. It consists of single-use heat transfer pads, which are adhered to areas of the patient's skin, and a control module that circulates temperature-controlled water. The control module is connected to the pads by flexible tubing. A commercially available temperature probe connected to the control module senses the patient's core temperature. The system can control the patient's core temperature by altering the temperature of the circulating water.

Summary of the technological characteristics of the device compared to the predicate device.
The Arctic Sun Temperature Management System Model 2000 and the above referenced predicate devices are thermal regulating systems as defined in 21 CFR 870.5900. These external systems consist of a device that is placed in contact with the patient and a temperature controller for the device. These devices utilize pads in contact with the patient. In these

devices, the microprocessor-based temperature controllers circulate water through the pads to regulate the patient's temperature. Patient temperature is monitored by YSI 400 series temperature probe.

Testing
Testing of the Arctic Sun Temperature Management System, Model 2000 Control Unit, included electrical safety testing in accordance with the IEC601/EN60601 series of standards and functional safety and performance testing.

Conclusions
Based upon the testing and comparison to the predicate device, the Arctic Sun Temperature Management System, consisting of the modified Arctic Sun™ Model 2000 Control Unit, performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2007

Medivance, Inc.
c/o Ms. Lynne Aronson
Director, Regulatory Affairs and Quality Assurance
1172 Century Drive, Suite 240
Louisville, CO 80027

Re: K071341
Artic Sun® Temperature Management System - Model 2000 Control Unit
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: July 13, 2007
Received: July 16, 2007

Dear Ms. Aronson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. STATEMENT OF INDICATIONS FOR USE (FDA FORM)

510(k): K071341

Device: Arctic Sun Temperature Management System

Indications for Use:

The Arctic Sun™ Temperature Management System is a thermal regulating system, indicated for monitoring and controlling patient temperature.

Prescription Use ___X___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071341

(Optional Format 1-2-96)